to the laboratory for the intent of performing an angioplasty with one of these balloons.

So I think our stance so far has been that we are going to keep all of the risks attendant to the entire procedure in the list here.

DR. HARTZ: I think, if we go there, there's a lot more things we would have to talk about, because there is just a myriad of other complications that really are just inherent to taking a patient to the laboratory to do coronary angiography.

For example, are they or are they not going to have a left ventriculogram. So I think contrast and anti-coagulation really -- maybe not so much anti-coagulation because of the new anti-platelet agents, but certainly contrast is part and parcel of the patient going for the angiogram.

The contrast in this procedure is contained within the balloon.

DR. LASKEY: Prior to advent of coronary angioplasty, every single risk in Section 2 applied as well, with the exception of balloon rupture, guide wire fracture, and one other here. Every single risk

was cited to the patients who were undergoing coronary angiography, but I'm not sure what that proves. It's inherent in instrumenting the coronary arteries.

DR. KRUCOFF: Yes. Renee, there are unique risks, too, for an angioplasty. You may extend the volume of contrast considerably. It may risk more of the osmotic complications or the renal complications in order to do so.

So I think the notion of keeping all the procedure lumped together in spirit is something I would support, and contrast would be included in that.

ACTING CHAIRPERSON TRACY: I think we have looked at -- If we look through this list, are there any other obvious big potentials that we are missing here?

DR. CRITTENDEN: Dislodging a stent that was previously placed?

ACTING CHAIRPERSON TRACY: That was a point I wanted to raise as a question. Do we want to add some language here about interaction with stents, potential interaction with stents?

DR. KRUCOFF: How about just adding that

to embolization or fragmentation of thrombotic or atherosclerotic or stent material, because that is ultimately what you are going to be doing if you dislodge it. You just sort of add it to that feature.

ACTING CHAIRPERSON TRACY: Okay.

DR. HARTZ: In view of your reference concerning exceeding contrast volume, we have to add renal failure, because it's specific from allergic reaction.

MR. DILLARD: Dr. Tracy, can I just add a point, too? I think, to the point about stent situation and whether or not we actually go in and we balloon where we already have a stent, one of the other questions, I think, that will help perhaps in the risks also is when you get to the point of the supplement data sheet where we are going to ask you for your recommendations on the indications for use prescribed, recommended or suggested in the devices labeling.

One of the other points that certainly came up was there appears to be three indications that the manufacturer potentially is after, and there was

some discussion on the part of the panel about whether or not there is actually enough data for some of those indications.

So I think that is part of what needs to be factored in, because that will have an impact also on the last point about the stent, potentially. Does that make any sense?

ACTING CHAIRPERSON TRACY: Yes. I would sort of favor at this point moving on, because we could just keep thinking up potential complications that -- you know, it could go on forever.

So if everybody is in agreement, we will move on to question number 3: "Have appropriate special controls been identified to adequately address the risks to health specific to PTCA catheters? If not, what additional special controls are necessary to reclassify PTCA catheters?"

The proposed special controls cited were guidance document and device labeling, and there has been many, many references to the fact that we think that the guidance document needs some updating. I think that is probably fair to say, too, for the

device labeling, and we have made comments throughout the proceedings as to specifics on that.

Any other comments on that?

DR. LI: I guess -- I completely agree with that. I just want to maybe emphasize the point that updating, in my case, I would prefer to see for each one of these tests a specific protocol, because it seems like right now there's kind of a -- for those that have devices, they kind of know what to expect; but if you are new to the area or something else changes, it's unclear exactly if everybody gets the same playing field.

DR. CRITTENDEN; Is it reasonable to standardize in vitro testing? Is that kind of what you are saying?

DR. LI: Well, maybe standardize is a little strong, but at least I think there ought to be a basic set of exact tests, number of specimens, how it's loaded, all the engineering tests you would need to do to ensure that everybody knows exactly what it is they are supposed to do without having to quibble and negotiate over it.

Then the last addition was the only thing I would like to see added to this -- and I guess Dr. Fearnot says they do some of this already, but again it's a little loosey goosey -- I would like to see specifically what I'll call combination testing.

For instance, burst strengths like after a fatigue test or after inflation/deflation, you know, things that were more closely -- maybe mimic the multi-factors that are played in the clinic should be added to this and not just straight testing of a brand new, perfect balloon device.

ACTING CHAIRPERSON TRACY: Okay. That is fair. Any other specific comments on this?

DR. KRUCOFF: I actually have a process question. As we make these lists, are we implying consensus across the group with the results of the answers to each of these questions or are we going to come back to whatever we agree to here and vote?

MR. DILLARD: Jim Dillard. What these three questions specifically, since they seem to be the ones that we struggle with the most as you are actually going through the supplemental data sheets --

the attempt was to try to get you to tackle them as individual units and not be confused once you saw them on the data sheets.

So that what we can do is apply the conversation you have already had when you are actually formally -- or Dr. Tracy and us are formally filling out what needs to be documented for the reclassification process.

So it was really an attempt to not have to redo this when we get there. You will, however, go through it, vote on each individual thing and see whether or not you have consensus on each question.

DR. KRUCOFF: Because then I would say at a minimum I think, as another special control, there would need to be a better post-market surveillance capability to ensure that what we are doing with testing and guidance documents, which I think are very problematic in themselves, doesn't translate to hurting people as it comes out beyond. I guess that's a specific control.

ACTING CHAIRPERSON TRACY: On the sheet that we have from this morning with special controls,

post-market surveillance is listed as a potential type of special control. It's not one that had been previously indicated as being appropriate to put in place, but I do agree that that's clearly appropriate.

Just if you want to refer to that sheet from earlier, the other things were performance standards, voluntary standards, post-market surveillance, user information checklist, patient information education guidelines, guidance documents, patient registries, still subject to 510(K) and design controls.

Any other of these that we think we need to discuss in more detail?

MR. DILLARD: Just one point, that those sheets -- you got those from, actually, the FDA training. Is that correct?

ACTING CHAIRPERSON TRACY: Right. That's right.

MR. DILLARD: Good.

ACTING CHAIRPERSON TRACY: See, you did good. We were listening.

DR. LASKEY: With respect to the

performance standards, where are we or what -- how much authority do we have to recommend real standardization across the industry? I mean, are we talking about getting all vendors in the same room to adhere to a common set of operating principles, much as they do in NEMA, for example? Is that what we are driving at here? What are we talking about for --

MR. DILLARD: Jim Dillard. I don't know exactly. You will probably want to have that discussion with the rest of the panel, but let me see if I can't clarify.

The two types of standards that we have are, number one, FDA promulgated performance standards which are something that I think, as you have heard in the training, are rather difficult and generally take many years, because it requires notice and comment and rulemaking from outside the agency.

The other type of standard that we generally refer to is a consensus standard, which would generally be developed by either an outside organization like an American Society for Testing and Materials or the International Standardization

Organization, the ISO organization, those types of organizations that generally develop industry-wide consensus standards.

If there is one developed, what the agency can do is recognize that as a consensus standard and use that in the overall clearance of medical devices. I don't think, however, this is the right venue necessarily to propose whether or not we need to develop a particular kind of standard, unless you absolutely think it's crucial as a special control. That would be the context that I would put it in here.

ACTING CHAIRPERSON TRACY: So in other words, at this point such a thing does not exist with regard to --

MR. DILLARD: That's correct.

ACTING CHAIRPERSON TRACY: Okay. But what we do wish to see is post-market surveillance, a guidance document that's updated, and labeling that is updated. Any other discussion on this?

Okay. Before we move on to the actual filling of the forms, I'd like to open up for public hearing and solicit any additional comments from the

audience. Okay.

If not, then I guess we will move on to our supplemental data sheet. Oh, the general form first, which is in your blue packet, the general device classification questionnaire. Each member of the panel will fill in an individual sheet and leave it for pick-up by the FDA here.

DR. HARTZ: Could I ask a question? When we fill these sheets out, are we to take into consideration all the comments we just made?

MS. MOYNAHAN: When you fill out those sheets, you could fill it out with your own comments. Then what Cindy Tracy is going to be doing is collecting the consensus comments from the group and putting them on one form which we are also going to be repeating up in the overhead.

MR. DILLARD: And to make it easier -- Jim Dillard again -- if you believe you have adequately addressed a particular issue, and if you can reach consensus amongst yourselves that what we have already talked about is what our general recommendation would be and just summarize it, the record will certainly

help us and will speak for itself, too, when we go back through it.

So it's not absolutely necessary, Dr. Tracy, that you write down every word of everything that you guys have discussed.

ACTING CHAIRPERSON TRACY: For a clarification, what is it that we need to vote on? Do we need to vote on the outcome of this?

MR. DILLARD: I would suggest going through and trying to fill out the sheet, see if you can't get a vote on the whole entire sheet and, if there are some particular issues where you have not reached consensus, you might want to try to vote on each individual one.

ACTING CHAIRPERSON TRACY: Okay. All right then, starting right at the top, the generic type of device that we are talking about is balloon catheters for PTCA, and the classification recommendation -- Mike, I believe you were about to make some recommendations.

DR. DOMANSKI: Yes. I move that we recommend that reclassification to Class II be

accepted or performed by the FDA.

ACTING CHAIRPERSON TRACY: Okay.

MR. DILLARD: Jim Dillard. You might want to just hold that, Dr. Domanski, until you actually go through this, see if the process brings you out to the same recommendation, and then I think you can do that.

ACTING CHAIRPERSON TRACY: All right. Is the device a life sustaining or life supporting? I think the answer to that would be yes.

Is the device for a use which is of substantial importance in preventing impairment of human health? Yes.

DR. HARTZ: I'm confused. I thought we were going to do these on our own and then we're going to get a consensus based on everybody's answers.

ACTING CHAIRPERSON TRACY: Do you want to take five minutes and fill it in, and then we will --

MR. DILLARD: No, no, no. Jim Dillard. Let me see if we can't work out a process here. This is the confusing part. This is the part that's the toughest every time we do this.

ACTING CHAIRPERSON TRACY: This is the

part that wasn't covered in training.

MR. DILLARD: It doesn't matter. Even when we cover it, we don't get it right.

My suggestion would be, just as you are going through this, Dr. Tracy, if it's an obvious answer, then I think you can certainly make a checkmark on it. If it may be a debatable point, you may want to have some discussion before you actually fill it in and then move on.

Then if you as an individual person don't agree with that particular assessment in the end, you can certainly make note of it on your own form so that we can enter that into the overall record.

ACTING CHAIRPERSON TRACY: Okay. So we are at question number 2: Is the device for a use which is of substantial importance in preventing impairment of human health?

My instincts say yes. Is there any debate on that?

Number 3: Does the device present a potential unreasonable risk of illness or injury?

DR. KRUCOFF: Yes. Potential.

ACTING CHAIRPERSON TRACY: Potential unreasonable risk.

DR. DOMANSKI: But the important word is unreasonable, and the answer is it's not unreasonable.

DR. HARTZ: What if there are more coronary aneurysms?

DR. DOMANSKI: Does the device present a potential unreasonable risk of illness or injury? Well, you have the thing well characterized, and we know the answer is no.

DR. HARTZ: The answer is yes.

DR. KRUCOFF: I think the answer is yes. I mean, it's a potential risk. To me, that's just an alert that we need to pay more attention to it.

Jim, what's the answer?

ACTING CHAIRPERSON TRACY: That's not very easy.

MR. DILLARD; It is not. It's sort of like -- It's kind of like the wording that we asked you to clarify of the particular device. It would be helpful if this is a little more specific, and we always get hung up here.

I think the interpretation here is to try to take a look at what is known about the product, and are there things that are unknown that potentially could be unreasonable for the patient population? If we believe that we know about the product, that there are reasonable risks because they are happening every day, I think, like the product is currently used, I think actually the answer to that generally, when we look at it from that perspective, is no.

This is a questionnaire, just to clarify, for both classification and reclassification. So that particular question, I think, is much more applicable when you are talking about a product where you really might not know very much when we were originally classifying products 20 or 25 years ago.

ACTING CHAIRPERSON TRACY: And unreasonable does not imply that it's a small risk.

MR. DILLARD: Correct.

ACTING CHAIRPERSON TRACY: The risk may be extremely high. It's just that we are not taking a Foley catheter and putting it in a coronary artery, which would be an unreasonable risk.

MR. DILLARD: Correct.

ACTING CHAIRPERSON TRACY: Okay. So with that understanding, I think the answer would be no.

DR. CRITTENDEN: I disagree.

DR. HARTZ: I just want to clarify one more time. I think the way we are doing this -- This is causing -- Maybe this is the standard way you do this, but this is biasing us all as to what we are going to answer on these questions.

MR. DILLARD: Well, let me just, you know, jump to the bottom line, which is it doesn't matter what you answer on this. You are going to go to the next question, and actually, the way classification works, it's irrespective on this one.

DR. HARTZ: So we can answer whatever we want, even if the consensus appears to be something else.

MR. DILLARD: This one really has very little bearing on actually reclassification.

DR. CRITTENDEN; Can I just make a point? Every time I get called to the cath lab as a surgeon and they say I'm not going to do this lesion, Mike,

you need to operate on him, then we are saying yes to this question, because the interventionalist presents that it's unreasonable in this patient to do an angioplasty. I think this is asking that same question.

DR. DOMANSKI: I don't think so at all, as a matter of fact. I think what they are asking is: Is there a potential for an unreasonable risk? For instance, the polymer causes cancer. You know, is there a chance that the polymer is going to cause cancer in a lot of people or something?

ACTING CHAIRPERSON TRACY: Can we just table the discussion on question number 3 until we move forward to number 4, because I think it doesn't matter in terms of the flow of this form what we put on number 3, if we could just for the moment table that or we'll never get anywhere.

DR. KRUCOFF: Number 3 is ad lib.

ACTING CHAIRPERSON TRACY: So did you answer yes to any of the above three questions?

DR. KRUCOFF: Yes.

ACTING CHAIRPERSON TRACY: Yes, we did

answer yes. So if yes, then go to item 7.

Is there sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness? If yes, check the special control(s) needed to provide such reasonable assurance for Class II.

My instinct would be yes.

DR. KRUCOFF: Well, I'm willing to acknowledge to everybody, I feel sort of like the outlier here, but I really am very troubled to answer this yes, and I think the answer to this question is no.

I think we have far more ignorance than knowledge about the balloon catheters that are already being manufactured. I think this is a moving platform. We are seeing this moving not only in what and how these balloons are manufactured; we are seeing it as a moving target in what kind of coronary anatomy, in the types of patients in whom they are being applied.

I think we have a need for a specific control of post-marketing surveillance that does not

exist. I think we have wholly inadequate reporting and appreciation of device failure as it exists now as a Class III device.

I think, to consider this adequate to support as knowledgeable special controls for a Class II device is a terrible assumption. I think we open the door to a Pandora's box from the manufacturing side.

I don't think there is any clear message to me that we will actually reduce the burden of resource use of FDA if new manufacturers step up. Inspections to evaluate new manufacturers are as or more laborious than the PMA supplements for new balloons to come forward, as it is.

So I just don't get it, and I really am very troubled by the whole package here, somehow that we know the clinical outcomes from clinical trials using catheters, none of which in the reports cited are even still on the market today; that we have the ability to keep track of balloons that come and go every six months with changing polymer designs, changing constructions, and can feel confident that we

have the specific controls to understand and report and appreciate whether we triple the mortality rate associated with this procedure.

We would never be able to detect it with the mechanisms that we have in place. So I am very concerned to answer this particular question.

ACTING CHAIRPERSON TRACY: Mike, you were the other lead reviewer on this. Do you share those concerns or do you have a different -- How would you answer number 7?

DR. DOMANSKI: Yes. I think it's time to declassify this device. I mean, these things are well characterized. They have been in extensive use. I think to maintain -- Oh, I'm sorry, seven -- six.

ACTING CHAIRPERSON TRACY: Number 7.

DR. DOMANSKI: Oh, I'm sorry. So I was going to answer those. I would say post-market surveillance. What I said was, in fact, post-market surveillance, device tracking and also testing guidelines were the three that I checked for this.

ACTING CHAIRPERSON TRACY: So you would answer that you do believe that there is sufficient

information to establish special controls.

DR. DOMANSKI: Oh, yes, absolutely.

ACTING CHAIRPERSON TRACY: And those would be the ones that you would specifically recommend.

DR. DOMANSKI: Correct.

ACTING CHAIRPERSON TRACY: Can I just take the prerogative of asking the rest of the panel members where they would stand on that? Dr. Laskey, question number 7?

DR. LASKEY: Yes. Well, i agree with Mitch Krucoff in spirit. I'm not sure we are here to impugn the system as it is, because we are also impugning the Class III approach to life as well. All those things are true.

Nevertheless, there is this 20 year experience with these catheters. I think that there is a standardized body of knowledge. There is a track record, a complication rate, and so forth that I'm not sure we are going to improve upon, even if we maintain the rigor of Class III.

I think, if we adhere to the spirit and the amendments, hopefully, that we make to

standardization and post-marketing surveillance that I would be in favor of reclassifying these.

ACTING CHAIRPERSON TRACY: Dr. Hartz? I'm sorry. Would you have any specific thoughts regarding the particular special controls that you would like to see?

DR. LASKEY: Yes. The post-marketing surveillance and certainly the performance standards. If that could be accomplished, I think that would be a quantum leap in the quality assurance of these instruments.

ACTING CHAIRPERSON TRACY: Dr. Hartz.

DR. HARTZ: Well, I am really, truly on the fence, because I came in here thinking I did not think this classification should be changed. But when you gave us this paper this morning concerning classification, and for Class III it says specifically -- and I was not really very aware of this -- probable benefit to health for a Class III, probable benefit to health outweighs any probable risk of injury or illness.

Firstly, now plain old balloon angioplasty

in a small artery, which is what we are talking about, I don't think the probable benefit to health outweighs any probable risk of injury or illness in that setting. I think it's a very -- It's a pretty minor procedure.

I really think the reason we are going through this whole process is to just get to stents, and this is just -- I'm not sure of my answer yet. Use of device will provide clinically significant results. I'm still not -- I don't believe the results will be all that clinically significant, because these patients are going to restenose, because these are small arteries with just a plain balloon.

So when I look at the definition that FDA gave us, this is not a very dangerous device.

MR. DILLARD: I believe you are speaking to, I think, and quoting basically what we consider to be the definitions of safety and effectiveness, I think; and that's generally how we look at them, certainly for PMA approval.

I think that these products, at least the products we are talking about that define this

category have actually already been proven to be safe and effective and, therefore, they are actually on the market, which is why they went through the PMA approval process.

So it's a little bit out of context for downclassification. It's not the exact identical standard. I think what we are saying is that can that standard be changed from each individual device has to prove that there is just those definitions you talked about, reasonable assurance of safety and effectiveness, to more of a generic category of products where we understand how they perform, and then are there other controls that could adequately control for the risks and the benefit of the product, which I think is really kind of the bottom line of reclassification.

So it is a change from saying each individual product has to be proven to be safe and effective to, no, a product can be proven to be substantially equivalent with certain controls in place. That's the philosophical change between what we are doing here.

DR. HARTZ: And in that context, I think if we classify this as II, the most important point, the most important on the list is patient registries, which I recently tried to find data for angioplasty in 1996, and ATC had 125,000 angioplasties listed for that year. That's absurd.

I mean, there is really no good registry except for Medicare patients. So I think that is the most important way we can get at some of this data.

DR. DOMANSKI: I guess, though, the question I have with regard to insisting on a registry is -- and, Jim, perhaps I misunderstand what the process would be, but I would propose that if somebody comes in with just a variation on their standard balloon catheter, marker is in a different place or something, to ask them to do a patient registry for that would be excessive, I think.

That's why requiring -- I mean, FDA can always require it if they want to, but I guess I wouldn't make it a generic requirement.

MR. DILLARD: I guess maybe one other factor to consider is, if by downclassifying this with

the special controls what we are doing is adding regulatory burden by the fact of adding patient registries and device tracking and post-market surveillance to something that currently doesn't exist, we are not going to have a whole lot of people coming in, based on that recommendation, and saying, hey, I now want it to be downclassified. You just upped.

Even though you put it in Class II, you just upped the requirements for what we have to actually do to prove that the product ought to be on the market.

DR. DOMANSKI: Well, I'm willing to remove the post-market surveillance, by the way, from my recommendation. Jim, doesn't that make sense?

MR. DILLARD: Well, just the reality check. I wanted to put it on the table.

DR. DOMANSKI: All right. Well, I'll eliminate that.

ACTING CHAIRPERSON TRACY: There currently does exist some post-market surveillance. Is that not correct?

MR. DILLARD: In general, we do not have a requirement of post-market surveillance. I think that it is more driven by -- Right now, we do have pre-market clinical information, but depending on what comes out of that pre-market clinical study drives whether or not there needs to be any post-market effort associated with it.

Again, what we are talking about here is a standard PTCA catheter with nothing fancy, no drug delivery, no other bells and whistles associated with it here.

ACTING CHAIRPERSON TRACY: So I think that is an excellent point, that we don't want to make this more burdensome than a PMA would be. At this point, if there is no post-market surveillance that is mandated nor are there specified performance standards, the only thing that I see concretely that we have are the guidance documents and the labeling.

Is that the current standard to which the new applications have been held? I wouldn't think it would be reasonable to make the standard higher than what a new application would require.

MR. DILLARD: Jim Dillard. Currently, what there would need to be is, certainly, a look at the guidance document, which we think is very important. I think the labeling is certainly something that has -- we have tried to standardize more and more as time goes on.

Then the other, of course, is the requirement in Class III products that there be a demonstration that there is reasonable assurance of safety and effectiveness. We haven't found a very good way for most applications to do that without a product's own clinical dataset to judge whether the product performs to this reasonable assurance of safety and effectiveness.

There have been very few, maybe one or two PMAs, that have ever been approved with only literature information, for example. It's rather limited.

So it is a standard change from that pre-market clinical experience to something where we understand about the product and we use other means to determine that it is reasonable.

ACTING CHAIRPERSON TRACY: And that really -- If I am understanding you correctly then, the only two reasonable special controls that we would have at our fingertips here would be the guidance document and the labeling, because other than that we would be recreating a new standard for a device that's been around for 20 years.

MR. DILLARD: Yes.

ACTING CHAIRPERSON TRACY: Okay. Dr. Li.

DR. LI: Yes. I guess I have a comment on that. If it's Class III, there is the strong option that the FDA would require a PMA, which has basically some clinical follow-up to it. So with or without a post-market surveillance, the PMA by definition provides the FDA with some clinical information.

If you go to Class II and you get rid of any kind of post-market surveillance of any kind, then we will never know how that device performs. There will be no clinical information for that device.

So I don't actually see it as being more burdensome, necessarily, because the post-market surveillance could have a time limit. It doesn't have

to be forever, but it seems to me not right that, if we downclassify, that we actually just stop looking at them completely.

ACTING CHAIRPERSON TRACY: Is that correct that a product that comes in with a 510(K) we could not ask them to have post-market surveillance? I think it's different to ask for post-market surveillance within an individual product versus some more global registry, which I don't think we can mandate, if the ATC has been trying for years to get a registry going and hasn't been able to.

Is it possible still within a 510(K) situation to have some request for post-market surveillance?

MR. DILLARD: Jim Dillard. Yes, it is. There are some other regulatory considerations, but I don't know how much detail you want to hear about, about whether or not something is a 510(K) versus a PMA and our ability to use post-market controls.

Let me try to sum up by just saying that I think Dr. Li's point is a very good one, I mean just in terms of surveillance in this particular setting,

I think, what we would be talking about would be some report of clinical information about the product and how it's used.

I don't know that you all would need to specify anymore than that, but I think, if you believe it is important -- and I'm not trying to guide you or lead you either way, but if you think it's important for the FDA to have some piece of clinical information, whether that is pre-market or post-market and whether or not part of this shift would be from the pre-market kind of data to a post-market surveillance setting and you believe that that would still be important, that would be a reasonable recommendation in a shift where we are going from a III to a II, even though we haven't been doing that, because we are changing from saying there is no pre-market, at least a priori no pre-market clinical data requirement, but now we are shifting that burden somewhat to the post-market arena.

That still doesn't, though -- If a little bit different design comes about or we have a question we are unclear about, FDA still could in the pre-

market notification process ask for a pre-market clinical study. That just wouldn't be what we would normally do with a Class II kind of classification.

So if that helps --

DR. LI: Just as a follow-up on that, I guess my concern again is for the future product where we may not know the consequence of a small -- what we perceive as a small design change or something that should be inconsequential. I mean, biomaterials is littered with devices with inconsequential changes that turned out to be very large clinical changes.

So I think, to go to Class II in one sense would be okay, if I had some sense that there was some clinical follow-up, that we didn't do something we didn't know we were doing.

ACTING CHAIRPERSON TRACY: That seems to be the consensus of the group -- at least I'm seeing heads nodding -- that we would feel more comfortable if there was some type of post-market report or clinical surveillance, whether you want to call it a post-market surveillance or if there is another more appropriate term, that that would probably be

reassuring for the panel.

DR. LASKEY: Let me throw another log on the fire. I don't see how we can do otherwise, frankly. I think that we are all uncomfortable, clearly. We are uncomfortable, because we can't see into the future.

Those of us that do this stuff every day know what the limitations of it are, and I think we are expressing this level of concern to the FDA. We are concerned, and we don't know.

Now we are trying to be good guys, but I think that the yellow light is clearly flashing.

DR. KRUCOFF: Yes. I definitely echo that same sentiment. I mean, we've been involved in developing the guidance and the ASTM. We are huge fans of this. This is a noble effort that has been a lot of blood, sweat and tears to bring as far as it has come.

My real comment is that right now I don't think either this guidance or the standardization of testing or any routine, already in place device related failure reporting, etcetera, are sufficient to

protect people who undergo these procedures from the unknowns of these small device modifications that may produce unforeseen effect.

That's really the voice of my concern. If this was a year from now when ASTM had a chance to come a half-step further -- I mean, it's close, and that is what makes this such a dilemma. You don't want to feel like we are holding everything back.

I think when you really sit down a look at what do we actually use right now as a guidance document that exists relative to this question, what do we use right now as standardized testing as it exists relative to this question, and what do we use for understanding what happens to people after devices through this path are released, that I think we should be conservative.

ACTING CHAIRPERSON TRACY: All right. I am going to keep trying to go around the table here in terms of just comments on number 7, whether -- Dr. Hartz, I didn't come down with a yes or a no for you on question 7. I don't know if you are ready to make a comment there or if we can come back to that.

DR. HARTZ: The answer is yes for special controls. I'm not quite certain what --

ACTING CHAIRPERSON TRACY: All right. We will move on then. I would say yes with special controls. Dr. Crittenden?

DR. CRITTENDEN: Yes, with special controls.

ACTING CHAIRPERSON TRACY: Dr. Aziz?

DR. AZIZ: Yes.

ACTING CHAIRPERSON TRACY: Tony?

DR. SIMMONS: Yes.

ACTING CHAIRPERSON TRACY: Dr. Li?

DR. LI: I guess it would be a highly reluctant yes, with specific special controls.

ACTING CHAIRPERSON TRACY: Okay. All right. The particular special controls that we've talked about would be the guidance documents with a close look at that to make sure it is updated, the labeling again with a close look to make sure that it is updated, report of clinical surveillance.

Then if we can jump down to question number 8, which is, I think, a thorny one: If a

regulatory performance standard is needed to provide reasonable assurance of the safety and effectiveness of a Class II or III device, identify the priority for establishing such a standard.

I would say that --

MR. DILLARD: Can I just jump in here? If your answer to number 7 is guidance, labeling and surveillance, the answer to number 8 is "not applicable."

ACTING CHAIRPERSON TRACY: Okay. All right, then I guess we have to just be happy or not happy, depending on who we are, with the answer to number 7 being, yes, with the three special controls that we've talked about.

DR. LI: Just to make sure, which three are those?

ACTING CHAIRPERSON TRACY: Guidance -- Updated guidance document, updated labeling document -- I'm not specifying all the individual things people, for example, have said --

DR. LI: I understand.

ACTING CHAIRPERSON TRACY: -- and some

type of post-market surveillance or report of clinical surveillance.

DR. LI: So just for clarification again, in Item 7 testing guidelines is the guidance document?

ACTING CHAIRPERSON TRACY: That would be within the guidance document.

MR. DILLARD: Just a point of clarification. Jim Dillard. I would check "other" there, and put "guidance document." Testing guidelines can be something different, actually, by definition.

ACTING CHAIRPERSON TRACY: But what he was particularly interested in would be encompassed within the guidance document.

MR. DILLARD: Under the guidance document, yes, which I would put under "Other."

ACTING CHAIRPERSON TRACY: Okay. All right. So then number 8 becomes "Not Applicable."

Number 9: "For a device recommended for reclassification into Class II, should the recommended regulatory performance standard -- How is that? I think it's not applicable.

"For a device recommended for reclassification into Class II, should the recommended regulatory performance standard be in place" --

MR. DILLARD: "Not Applicable."

ACTING CHAIRPERSON TRACY: Not applicable. Okay. Number 10: "For a device recommended for classification/reclassification into Class III" -- not applicable.

Okay, Number 11a: "Can there otherwise be reasonable assurance of its safety and effectiveness without restrictions on its sale, distribution or use, because of any potentiality for harmful effect or the collateral measures necessary for the device's use?"

MR. DILLARD: Jim Dillard. Do you want the English on that?

ACTING CHAIRPERSON TRACY: Could you tell me?

MR. DILLARD: Yes. The English on that is do you believe it should be a prescription device.

ACTING CHAIRPERSON TRACY: Yes.

MR. DILLARD: Okay.

ACTING CHAIRPERSON TRACY: That was pretty

easy.

MR. DILLARD: So the answer, actually, is "No" to that question.

ACTING CHAIRPERSON TRACY: The answer is "No."

MR. DILLARD: Yes, because it's can there otherwise be reasonable assurance of its safety and effectiveness. It's no. So then this specifically 11b, you need to state to what extent there needs to be the prescription information.

ACTING CHAIRPERSON TRACY: Okay. "Identify the needed restriction(s): Only upon the written or oral authorization of a practitioner licensed by law to administer or use the device; use only by persons with specific training or experience in its use" --

MR. DILLARD: Clarification here? Jim Dillard. Do you want the clarification first?

ACTING CHAIRPERSON TRACY: Yes.

MR. DILLARD: This is a hierarchy. So the general what we consider to be prescription device is that first box, and then what you are talking about is

more and more specific restrictions on either who and/or at what facilities this particular kind of product should be needed.

So if your answer is that just the standard what we have now, which is your general prescription statement for the use of the product, applies, then all you need to check is the first box.

If you think it needs to be more restricted than that, then you need to check subsequent boxes also.

DR. KRUCOFF: Specific training.

ACTING CHAIRPERSON TRACY: Why do you say that, Mitch? I think that you do need specific training for it, but there are people in the community doing this who may predate the era of specific training.

DR. KRUCOFF: Well, I think there are ACC, AHA recommendations right now that make it pretty clear that some degree of training and practice are advisable, and I happen to agree.

DR. LASKEY: After 2003, this is a non-issue. You have to have received board certification

to do this.

ACTING CHAIRPERSON TRACY: But this is 2000.

MR. LASKEY: I'm just letting you know what is down the pike, and I agree with the current sentiment within the profession. ACC, AHA guidelines are pretty clear, but they will be even clearer in 2003. Specific training could include grandfathered in. I mean, I don't think that necessarily means there are operators currently in practice who would be left out.

MR. DILLARD: Jim Dillard. Maybe I can do a little bit more here, which is, I guess, how we generally take a look at this, is that unless there is a real specific reason to have special training by the practitioner or only certain facilities for some reason are going to be capable of utilizing the technology, these are pretty restricted types of activities where the FDA generally backs out of that, unless it is absolutely necessary, and lets the practice of medicine designate who should be the appropriate person and/or facility to perform

procedures and utilize the technology.

So this is really taking an extra step to say, basically, the FDA needs to step in even more than they currently do, because again these are available technologies, to provide more regulatory oversight and more control, which is going to be really tough on a Class II product. I just need to say that.

It's much easier for a Class III product to mandate who actually should be performing the procedure and at what facilities, if you check either one of those boxes.

ACTING CHAIRPERSON TRACY: And how is it currently? How would you answer this currently?

MR. DILLARD: Currently, it is just the first box that is checked. That is as far as we go, which is saying that you need a prescription statement.

ACTING CHAIRPERSON TRACY: First box?

DR. HARTZ: I checked two, two boxes.

DR. DOMANSKI: Yes, but you know, the difficult is they are not going to do that, because

you are expanding the indications over what is presently in place for more dangerous devices -- right? -- I mean, Jim, in effect?

MR. DILLARD: I'm not quite sure I understood that.

DR. DOMANSKI; One can approve something that is a Class III device without requiring what would be required if you checked one of the other two boxes.

MR. DILLARD: Yes. I got it this time.

DR. DOMANSKI: So in effect, we are making the standard more rigorous for a device that we are declassifying, because we say it's safer.

ACTING CHAIRPERSON TRACY: If we check both boxes.

DR. DOMANSKI: Yes, if you check more than one -- more than the top box. I mean, you can do anything you want, but it makes absolutely no sense for the FDA to actually do that.

MR. DILLARD: Yes. And actually, honestly, in the Class II arena we don't generally restrict devices beyond prescription use, because that

is really what Part 801 of our labeling regulation gives us authority to do and not go beyond that.

So it's only in those cases where you have a specific technology. It's a PMA. The panel and FDA both agree that there needs to be some very specific and rigorous oversight by the agency about who should practice with that particular product is where this really applies.

ACTING CHAIRPERSON TRACY: So with that sort of spirit, it seems as though only the first box is appropriate. Does that seem correct? All right.

I think at this point we are to take a stab at voting on this, or not?

MR. DILLARD: I think I would go ahead and vote on the whole first one. There are two separate documents. So I would go through and vote on this one first, and try to put this one to bed.

DR. HARTZ: Could I please ask one question, just before we vote?

Why are -- I've faced this dilemma many, many times coming to these meetings. Why is a registry more onerous than post-market surveillance?

I can't -- We really lack registries for a lot of devices and procedures.

I mean, I really think that's what we need as clinicians, and for some procedures we voluntarily have registries all over the surgical arena. Why shouldn't that be something that, I mean, we force the cardiology communities to do, the cardiology societies to do that, rather than have FDA do it, because that certainly seems it would make a lot more sense than post-market surveillance.

Here we have a device that is very, very safe except there are a couple of unknown things on the horizon such as false aneurysm of the coronary artery. This is a very difficult place to be in, when we know that we can't have the data, and we are not going to get it in five years to know if we did the right thing sitting here today.

MR. DILLARD: Let me try to answer a couple of things. I always think of patient registries as actually a very specific subset of one of the types of tools we have available to us for surveillance.

So I think of post-market surveillance as really a broader entity, which could include registries, but it could include other types of mechanisms that could be utilized to look at gathering data on a particular product or surveilling the product.

Registries, at least the things that we always hear at the agency -- there's a couple of problems with them. Number one is that, if you're really, truly out to answer a question, registries may or may not actually answer it. So depending on what the question is, you have to take a real close look at that particular use of a tool as a registry is to do.

Number two is that who is going to manage it? Registries are expensive. There is a cost factor associated with it, and FDA, if we are not really addressing a specific issue in the registry, we really do not have much authority to go out and mandate a registry just for the sake of having a registry.

So generally, I think the professional societies and/or a manufacturer decide if that is appropriate and if there is a need for it.

A registry per se, at least the way we have utilized them, is a data gathering mechanism that has been used in support of some indications for use. So it is a more robust data gathering tool than some of the surveillance tools we utilize.

So if you are saying here you think you really need a robust data measuring device or tool to utilize, you could certainly say that, and you can say that by way of the record, or you could be more specific and talk about registries.

By saying to us, we think we need post-market surveillance, that's giving the agency some flexibility to take a look at either individual manufacturers or the overall product category itself to really look at what is the most appropriate tool to answer the questions we need to answer for a surveillance situation.

So all I would say, in short, is that registries are one of the mechanisms for surveillance that can be utilized, but there's limitations to mandating it.

ACTING CHAIRPERSON TRACY: Dr. Li?

DR. LI: Yes. Steve Li. Is there a short answer to what is specifically device tracking? Is that just tracking where they go or does that have anything to do with the fate of that device?

MR. DILLARD: Tracking, when we generally think about it, we mean tracking to the patient, so we know which patient got which device.

DR. LI: So if we really wanted to know, for instance, how many balloons actually ruptured, which one of these methods would get us closest to that number?

MR. DILLARD: Surveillance.

ACTING CHAIRPERSON TRACY: The report of clinical surveillance.

DR. KRUCOFF: Jim -- Krucoff -- can I ask you honestly to continue to expound on what the panel's assumption is by checking the box post-market surveillance, and what the reality of FDA using post-market surveillance as a tool in Class II?

What percentage of patients do you think actually would be followed or any kind of clinical follow-up, or would you have the resources or the

time to go out and get -- We are aware of Class III post-market surveillance that has been very difficult to achieve and even more difficult to achieve at any enforceable level.

Other than the palliative conscience part of checking that box on this form, can you tell us as a committee what you really think post-market surveillance recommendation from this panel would translate to, if this is a Class II device?

MR. DILLARD: Let me give the reality of pre-market as it currently stands today. Maybe that will help identify what post-market might be reasonable.

Pre-market, currently, I would say that the -- certainly not the standard, but the last couple of PMAs that have come through have been 150 patients open-label looking at basically the performance of that particular PTCA catheter.

To have anything more than that --

DR. KRUCOFF: That's for a supplement?

MR. DILLARD: That's for an original PMA, original PMA of a standard balloon like this.

Supplement may not even need any clinical data.

DR. KRUCOFF: It may just be bench.

MR. DILLARD: Maybe bench data. So I think, if the reality here was to try to answer anything more than what we otherwise would answer with 150 pre-market patients in a post-market period, again I think the burden shifts dramatically from what we are trying to do in this.

ACTING CHAIRPERSON TRACY: Is the post-market surveillance, as we have been talking about it, this report of clinical surveillance -- is that true post-market surveillance or is that "other"?

MR. DILLARD: I think we have always interpreted checking the post-market surveillance box enough to be broad enough that we have room to work with the manufacturer.

ACTING CHAIRPERSON TRACY: Okay. If there is no more discussion on that, I would like to try to vote by blocks here on these questions. I will take a couple of easy ones first.

Question 1 and 2: Is the device life sustaining or supporting? The answer that seemed to

have consensus is yes. Is the device for use which is of substantial importance in preventing impairment of human health? The answer that we came up with was yes.

How do we do this?

MS. MOYNAHAN: Are we polling individual members at this point or are you just getting the consensus?

MR. DILLARD: Jim Dillard. I think you actually read number 2, didn't you?

ACTING CHAIRPERSON TRACY: Yes. I want to do one and two together. My intent was to get the actual vote, because I think we've gotten consensus so far.

MR. DILLARD: Great. Great. Perfect.

ACTING CHAIRPERSON TRACY: So all in favor of numbers one and two being answered as yes? It looks unanimous. No opposition there.

Question number 3: Does the device present a potential unreasonable risk of illness or injury? My answer would be no, and I will take votes for no as the answer to that, remembering that

unreasonable means does not imply that it is low risk. It means that it is anticipated risk. Okay.

MS. MOYNAHAN: So was that unanimous?

ACTING CHAIRPERSON TRACY: No. Number 3, we are now voting no. The people who are voting no for number 3 are now raising their hands.

MS. MOYNAHAN: That's four no.

ACTING CHAIRPERSON TRACY: And those who say yes?

MS. MOYNAHAN: That's five, yes.

ACTING CHAIRPERSON TRACY: Okay. Regardless, the answer to number 4 has to be yes, which brings us down to number 7: Is there sufficient information to establish special controls to provide reasonable assurance of safety and effectiveness? If yes, check the special controls needed to provide such reasonable assurance for Class II.

We have checked post-market surveillance and "other," and "other" is guidance documents with all the provisos stated previously, and labeling. So there's three things that we are recommending as special controls.

Now all those who would answer yes to this question with those particular special controls?

DR. HARTZ: List those three again.

ACTING CHAIRPERSON TRACY: Post-market surveillance to be sort of hammered out --

DR. DOMANSKI: I thought we did away with post-market surveillance.

ACTING CHAIRPERSON TRACY: No, we did not. We said that it would be hammered out by the FDA in terms of what type of clinical surveillance that that would imply, not to make it more burdensome than a new PMA. The other two special controls were the guidance document that would need to be updated with the particulars of testing and so on, and an updated version of labeling. Those were the three special controls that we had been discussing.

DR. LASKEY: The latter two are mentioned throughout the petition as though it is assumed that is going to happen anyway. Do we need to then confer legitimacy in this manner? Isn't this going to -- It's underway or it's halfway done or you're almost done?

ACTING CHAIRPERSON TRACY: I think we are saying that it has to be done. If our answer is going to be yes, I think we are saying that it has to be done.

MR. DILLARD: Jim Dillard. I think the short answer to your question is that, yes, we will do this, irrespective.

DR. LASKEY: And what happened to performance standards? Did that not make the cut?

ACTING CHAIRPERSON TRACY: I'm sorry?

DR. LASKEY: What happened to those who wanted to check performance standards?

ACTING CHAIRPERSON TRACY: How about if we just take 7 as yes or no. Let's just do the yes or no part first. All right, seven yes?

MS. MOYNAHAN: Seven yes.

ACTING CHAIRPERSON TRACY: Seven, no?

MS. MOYNAHAN: Just one.

ACTING CHAIRPERSON TRACY: Post-market surveillance, those that would like post-market surveillance? If you are in favor of having post-market surveillance?

MS. MOYNAHAN: Five in favor.

DR. HARTZ: Wait. I'm so confused.

ACTING CHAIRPERSON TRACY: We just have indicated that we do think that there is sufficient information to establish special controls. Now we are going to examine the specific special controls.

I thought that earlier we had a consensus on it, but I think that there is some -- there may be some people who would like to express a view, for example, that performance standards should be established. So we will take each of these individual special controls at this point and vote individually on them or indicate your preference on them, if that is okay.

MS. MOYNAHAN: We only need to capture the yeses of it on this question.

ACTING CHAIRPERSON TRACY: All right. I think then, if we don't need to vote on that, you have a sense that there is consensus on at least those three. There's still some concern.

MR. DILLARD: There isn't consensus, but I think this is the opportunity for people to make

their own -- I mean, if you are with the consensus, you can check post-market surveillance, and under "other," you can put guidance and labeling.

If there are other as individual special controls that you would recommend, I would say that is what you can check individually and put down on the particular sheet.

ACTING CHAIRPERSON TRACY: At this point we have simply voted for yes.

MR. DILLARD: At this point, yes. Correct.

ACTING CHAIRPERSON TRACY: By definition then, question number 8 becomes not applicable. Question 9 becomes not applicable. Question 10 becomes not applicable.

Question 11a with the translation became no. I don't think that is necessarily something to vote on, is it? I don't think so. And 11b -- let us go ahead and vote on that: Identify the needed restrictions.

Let me just say, is there anymore discussion on that or is there a consensus that we are

going to check the top box, "Only upon the written or oral authorization of a practitioner licensed by law"?

DR. HARTZ: I'm not in that consensus, because I can't even imagine that we could say that this device should not be used by persons with specific training and experience in its use.

ACTING CHAIRPERSON TRACY: So that becomes, I think, a minority opinion that would be stated in your filling in of the document.

Then we will move along to the supplemental data sheet.

MS. MOYNAHAN: Jim, do we have to go back to the classification recommendation at all or is that implied by where they went?

MR. DILLARD: Yes. Then I think you just need to fill yours in, Dr. Tracy, about what that means, which is I think, if you believe that there is sufficient information to establish special controls, then the classification recommendation would be for Class II.

ACTING CHAIRPERSON TRACY: Right. Okay.

Okay, then supplemental data sheet. I

think here let's just try to summarize the day's discussion. We are still talking about the PTCA balloon catheter. What is the answer to number 3? It's not an implant. These are tricky questions.

MR. DILLARD: Actually, in this case we have two definitions of implant. We have a short term and long term definition of implant. It is either greater than or less than 30 days. This one certainly is not greater than a 30 day implant.

I would say that this -- That's a good question. I would consider this to be a short term implant.

ACTING CHAIRPERSON TRACY: So the answer is yes.

MR. DILLARD: Yes.

ACTING CHAIRPERSON TRACY: Okay. All right, number 4: Indications for use prescribed, recommended or suggested in the device's labeling that were considered by the advisory panel.

MS. MOYNAHAN: That would be the recommended wording, I think.

DR. LI: Madam Chairman, can I request a

five-minute break? Three minutes?

ACTING CHAIRPERSON TRACY: Okay, five-minute break.

DR. LI: Thank you.

(Whereupon, the foregoing matter went off the record at 3:58 p.m. and went back on the record at 4:08 p.m.)

ACTING CHAIRPERSON TRACY: Okay. Our seven-minute five-minute break is now over, and we are going to resume with attempting to fill in the supplemental data sheet, and we are still talking about the generic type of device as the balloon PTCA, and we have decided it is a device of implant.

Question number 4: Indications for use prescribed, recommended or suggested in the device's labeling that were considered the advisory, and I think the FDA has something they want to put up for that.

This is the current indication: Intended for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the

purpose of improving myocardial perfusion.

MR. DILLARD: Jim Dillard. And I think we have got one other comment that we want to make based on the sponsor's presentation today, and I would like to call Chris Sloan up, because I think we want to talk about the two other pieces of the indications for use that the sponsor put forward.

MR. SLOAN: In addition to the indication posted on the screen, the sponsor has posted two other indications that weren't in the petition but were included in their presentation.

The second one would be: Balloon dilatation of a coronary artery occlusion for the purpose of restoring coronary flow in patients with ST-segment elevation, myocardial infarction.

I believe there is one sponsor which currently has that indication in their approved labeling.

The second -- well, the third indication in total, an additional one that the sponsor proposed was: Balloon dilatation of a stent after implantation.

That indication is subtly different from the approved indication that several manufacturers have, which is for the post-stent deployment indication -- post-deployment stent expansion indication.

So if the stent needs to be tacked up to make it uniformly expand in the vessel, sponsors do have that indication which has been obtained based on bench studies and, in one case, a clinical study has been performed.

I think the distinction that needs to be made based on this last proposed indication is that balloon dilatation of a stent after implantation could imply treatment of an in-stent restenosis with a balloon, and we need to have -- if the panel would please clarify if that is on the table at this point and just have some discussion along those lines.

ACTING CHAIRPERSON TRACY: Are there any devices that are currently requesting approval specifically for dilatation of in-stent restenosis that do not include brachytherapy or other types of therapy? Are there any balloons that are just going

for approval for that?

MR. SLOAN: No.

ACTING CHAIRPERSON TRACY: No.

DR. HARTZ: So which indication are we talking about? Are we talking about acute or in-stent stenosis?

MR. SLOAN: The three indications on the table --

DR. HARTZ: The first and the second, I think I'm pretty clear, but the last one that you mentioned, what is that?

MR. SLOAN: The last one, which is currently approved, is for an acute situation. So you have just deployed a stent, and you take either the stent delivery balloon, which has just delivered the stent, or another angioplasty catheter and post-dilate the stent to get complete opposition of the stent along the vessel wall.

So it's just an acute procedure. It would not be after some time that the stent is implanted to treat some type of in-stent restenosis.

DR. KRUCOFF: Can I just ask a procedural

question, Jim? If we list multiple indications for a 510(K) sort of process, is FDA still in a position to narrow that field for any given product?

As an example, if someone comes through with what I will crudely call a medium compliant sort of balloon where we are characteristically -- or something with a rated burst at eight or ten atmospheres, and we characteristically go to 14 or 15 atmospheres to post-deploy a stent, are you all in a position, if we list one indication with multiple components to it, to sort out which the "yes" and which the "no" would be?

MR. DILLARD: Well, let me talk a little bit to all three of these, because I think there is a difference potentially between what you currently see up here, which was the original indication for use, versus what I would consider the two other indications here where not all manufacturers have broadly petitioned us through an application to actually ask for those indications.

A couple of things here: If this is the indication that we currently are looking at and decide

to reclassify this particular indication, the current 510(K) process allows for people to come in and submit an application to the agency with other supporting data to try to get expansions of indications for use. That happens in the PMA process, just like that does in the 510(K) process.

If you actually include the other two indications as potential indications under this reclassification petition, what you are suggesting is that the data is widely available in those areas, that it can be broadly supported across anybody who would come in and petition us or submit an application under 510(K) to get that as a clearance.

Those indications which are currently here are indications that we would say, given the way we define the device, no additional clinical information would generally be necessary for those kinds of technologies.

So it does have a clear difference in meaning, whether you want to include them or exclude them, as to how broadly we would look at that.

ACTING CHAIRPERSON TRACY: I think one

thing that seems to have come through clearly to me in the discussion today is that we do not have data for in-stent restenosis. I think that might be an area that I would have some reservations about including that in the indication. However, the other two are, I would think, fairly generic for angioplasty balloon catheter for the indication as stated there, and also for the St-segment elevation or acute MI seem to relatively generic.

I think the tack-up of stent during stent placement is probably a fairly generic thing. Is that -- Do the angioplasty people agree with that? No? Yes?

DR. LI: Just as a clarification, for the retacking of the stent, that includes putting in a brand new balloon to do that or you just --

ACTING CHAIRPERSON TRACY: Yes. Yes.

DR. LI: I guess my only issue there is there is no in vitro testing that indicates how that balloon is going to perform in combination with a stent, given that there are many different balloons and many different stents. There is no information

whatsoever.

DR. HARTZ: These are now very relevant clinical situations where they deployed the stent, and the stent still is not tacked up.

DR. LI: I understand.

DR. HARTZ: You just do whatever you can, and we're just talking about using this particular balloon. Same thing with ST changes. For CSE changes you got to treat them.

DR. LI: I understand that issue, and I'm not saying you shouldn't do it. I'm saying that, if you are going to do it, you are going to have to roll in several -- I would rather see you roll in several in vitro tests that, when you do it, you don't use the wrong design or the wrong balloon manufacturer in combination with some stent.

MR. SLOAN: I can address Dr. Li's comment. We have acknowledged that our guidance document is a living document, but not as living as we hope it to be. We do have additional requirements if a sponsor is pursuing a post-appointment stent expansion indication.

We do require that the sponsor do balloon fatigue and rated burst pressure testing within representative type of stents to get that particular indication. That is not currently mentioned in our guidance, but it is a working policy within our division to ask for that information.

ACTING CHAIRPERSON TRACY: So the only question would be whether we sort of globally -- This is where the guidance document really would need to be very carefully evaluated and updated. Do we accept that sort of global pass-through or do we still require that as a -- suggest that as a separate issue?

DR. LI: I have a comment on that. I am already uncomfortable with the loosey-goosiness of actually what is written in front of me. I am even more apprehensive about -- I know they are working hard on these, but to approve -- kind of blanket approve a guidance or a test that I haven't seen or know anything about would be a stretch for my part.

So I think it's good that it is coming, but, certainly, I would like to see what it is and the extent of it before I say that it is safe and

efficacious for a clinician to use.

ACTING CHAIRPERSON TRACY: And it is legitimate for us to recommend reclassification for the indication -- first indication without reclassifying it for the other indication that pertains to stent.

MR. DILLARD: Yes.

ACTING CHAIRPERSON TRACY: How about ST-segment infarct or -- ST-segment elevation or acute myocardial infarction? Do we feel comfortable enough to say that that's globally approved for reclassification for that particular indication?

DR. KRUCOFF: Well, I'll just continue my wet blanket voice, I guess. But with respect, I hope, to recognition that the acute MI patient population are the most vulnerable patient population that we treat in the cath lab, and I think wherever and however we open doors to products emerging into the marketplace, they may be a little slower or a little bulkier or have other new features that we don't fully appreciate through human experience, that this is the patient population who, knocking off thrombus rather

than dilating it, etcetera, etcetera, are the most vulnerable population we have.

With the same sort of conservative tone with the efforts involved in a lot of the evolution of these guidance documents and the evolution of our standards of measuring materials and predicting or, hopefully, narrowing the in vitro to in vivo gap as it exists today, I would wonder or suggest even that maybe this particular indication would be worth deferring from this pass and seeing how reclassification in general in a more elective population goes for balloon products, rather than simply opening the door with that indication.

ACTING CHAIRPERSON TRACY: What percentage of current balloons have the acute infarct, ST-segment approval? Is it 80 percent or ten percent?

MR. SLOAN: One manufacturer.

ACTING CHAIRPERSON TRACY: One?

MR. DILLARD: One. Yes.

ACTING CHAIRPERSON TRACY: Okay. Renee?

DR. HARTZ: Could you explain to us, if you have a patient today and they are having ST

changes or the stent isn't tacked up, and the device you want to use or the only device you have available to you is not approved, do you go out and get consent? What do you do? If there is only one device that is approved currently for this purpose, does every single cath lab have that balloon?

DR. KRUCOFF: No. I think we talked about this a little this morning, Renee. I think actually usage frequently involves products off-label.

DR. HARTZ: So if you did use this device and it was off-label, would you then later report it, if it was a Class III device?

DR. KRUCOFF: Probably not. Again, I think in individual cases -- I think it's one thing to do it systematically, gather data, do research. We talked, again, about them. You need the IRB approval, etcetera.

ACTING CHAIRPERSON TRACY: But, you know, the practice of medicine would suggest that acute angioplasty or acute intervention is better than other modalities. So in a way, we are -- You know, this one I feel more comfortable, even though there is only

one. I would have felt better if you had said all of them or most of them have this indication, but I wonder if this is an anomaly of how things have been regulated up until this point, and maybe this is an opportunity to correct this anomaly, since I would say that, if there is only one manufacturer that has that particular approval, then the overwhelming majority of these things must be being done off-label at this point, and that doesn't seem reasonable to put anybody in that position, if it is an indication that has very wide published acceptance to it.

So I think it's a pretty acceptable and standardly done thing to do that. Again, we are not changing any of the parameters that go into the initial development of the balloon. We are not saying we're making less good balloons for these purposes.

I would favor passing on the first two, the standard and the ST-segment elevation/acute infarct. I do have reservations about the stent as well. I would not want to downregulate that.

Can we -- Do we have any type of consensus? I think we all have a sense that we do not

want the stent reclassified, but how about -- and I think we have a consensus that number one would have to be reclassified. The only one that I think at this point is of any question is the ST-segment elevation/infarct. Any consensus on that?

Mitch, I know you are the wet blanket here.

DR. KRUCOFF: The only other thing I'll mention about a higher -- slightly higher regulatory bar is that it does help us create data. I mean, again not only could you look at the anomaly the other way around, but you could say the only data we actually have about balloon performance and acute MI in a pretty organized fashion came from the fact that to get that indication required work done in humans, and we are opening a door to balloons that come through bench testing, not just idiosyncratically but consistently as an approved indication finding their way into acute infarction arteries.

ACTING CHAIRPERSON TRACY: But the reality is that nobody cares right now in the community. They don't care that the device that they are using is not

approved. They are using them, and it seems highly unlikely that a company is going to go back and say I must have this indication when their product is selling very well without the indication.

So I mean, the only chance I see at this point in picking up data is on some type of post-market surveillance, which we have already requested, and that could be part of the post-market surveillance that we want.

I just don't see us going back and revisiting this issue, since it is clinically acceptable at this point.

Dr. Li?

DR. LI: I obviously don't know enough about the clinical indication to lend a comment here, but I will say this, though, as a comment. I think there are numerous devices in other areas that are used off-label that have never been approved, and they go on by the thousands or tens of thousands annually. But one of the reasons they don't get the formal approval is nobody has been able to essentially meet the criteria of a valid scientific set of data that

says it's okay. So they kind of let sleeping dogs lie.

So if you as a physician think that is the best way to treat the patient, then so be it. Go treat the patient that way. But I think if you blanket say it must be okay because we are all doing it, you know, and there is no data to support one way or the other, then I think that's not a great reason to add it as an indication.

ACTING CHAIRPERSON TRACY: I think, though, the practice guidelines, which are pretty well researched guidelines, would support primary intervention for acute infarct. So it is not just based on standard practice. It's based on practice guidelines.

DR. LI; No, but this is using a particular device, though, for that procedure. Right? So if you say this is indicated for that, I would take that to mean that any one of these, however many balloons there are, could be used in that application, bar none, and I'm not sure there is any valid scientific evidence.

That might be true. I just don't see any valid scientific evidence that would say unequivocally it meets that criteria.

ACTING CHAIRPERSON TRACY: All right. Well, there you have it. Any other comments from the panel?

DR. LASKEY: I'm not sure it's worth drawing a line in the sand over this one. There is over the stent issue, but this issue -- 99 percent -- I didn't know this either, that the vast majority of balloon catheters are unapproved for acute MI intervention. I didn't know that.

So that 99 percent of balloons used for infarcts are unapproved. So be it. It's not worth drawing a line in the sand on this one.

DR. CRITTENDEN; So you are suggesting not to have it as an indication?

DR. LASKEY: No. To allow it in.

DR. CRITTENDEN: To allow it in.

ACTING CHAIRPERSON TRACY: I think I would favor allowing it in, because it does help get rid of this crazy dichotomy where 99 percent of what we are

doing is of-label.

DR. HARTZ: I would say exactly the same statement for the stent that is not adherent, because the sicker the patient is, the more off-label devices are going to be used. So I would say for these -- These are even more potent indications for using whatever balloon you can get. This is just too soft. The other two are very sick patients who need something done. I would say the more devices we approve for that, the better. So I think in surgery, putting it somebody who is dying, you didn't used to call the FDA until after it was in. They knew that.

ACTING CHAIRPERSON TRACY: Okay. I think we have a consensus on one and two. Number three, unless there is a swing in the feeling, then we will just go with a minority opinion on that.

Number 5, identification of any risks to health presented by device. I think we have covered that this morning with the list that we went through on the initial questions. We will just refer back to that, I think.

Number 6, recommended advisory panel

classification and priority: Classification II. I have no clue what priority means.

MS. MOYNAHAN: High, medium or low.

ACTING CHAIRPERSON TRACY: High, medium or low?

MR. DILLARD: Jim Dillard. This is generally for Class III. We need by statute whether it's high, medium or low. But if you would like to give us a recommendation about what you think by way of our resources whether we should put a lot, a medium or not too many resources in trying to do this might be a helpful recommendation from you.

ACTING CHAIRPERSON TRACY: Into the reclassification or into the other components of it?

MR. DILLARD: Into finishing up the reclassification, because this is by far only part of the process, not the whole, entire process. So --

ACTING CHAIRPERSON TRACY: I would think that, given that this has been -- The use of these devices has been in place and stable with the current types of indications and risks, etcetera, that we are discussing here, that we are not facing a critical

issue that needs to be resolved urgently.

So I would think that this would fall into the medium to low category. I don't know what low means. If low is five years, that is probably not reasonable, but somewhere not urgently pressing strikes me. Is that fair?

DR. CRITTENDEN: Medium.

ACTING CHAIRPERSON TRACY: Medium? Medium it is. Okay.

"If device is an implant or is life sustaining or life supporting and has been classified in a category other than Class III, explain fully the reasons for the lower classification with supporting documentation and data."

I think that is what we have been doing for the last several hours. So I think we will just refer back to the comments from earlier, and we have indicated the special controls that we want to have in place.

Number 8, summary of information, including clinical experience or judgment upon which classification recommendation is based: I think all

of the proceedings so far today have been part of this decision making, and there is a fairly extensive list of references that were provided by the manufacturer as well.

Number 9, identification of any needed restrictions on the use of the device: We had indicated in 11a of the general device questionnaire that we thought that this was a device that required -- It's actually 11b, I think. Right? 11a? Okay.

It is a prescription use device, basically.

Okay, question 10, If device is in Class I -- So that is not applicable.

Question 11, existing standards applicable to the device, device subassemblies or device materials: There are not specific existing standards.

I believe that's it. Vote? All right. We need to vote on this supplemental data sheet. Let me just say what we are voting on. We are voting on the supplemental data sheet, and the majority of it we are just voting on what has already been discussed.

The only one, question 4, is where there

is some maybe controversy. I believe that there was consensus, though, that the original indication plus the ST-segment or infarct indication we would advise reclassification from Class III to II, and I believe there is consensus that we are uncomfortable reclassifying it for stents.

So we are voting on this, whether we approve the data sheet as filled in at this time. All in favor?

MS. MOYNAHAN: Can you raise hands, and I will count. So six in favor. Opposed? And one opposed.

DR. HARTZ: Actually, since I have that one difference, I should oppose also, because I have this one --

MS. MOYNAHAN: So five in favor, and two opposed, and then we have lost a voting member, Dr. Aziz. He stepped away.

DR. HARTZ: There's no place for a signature on this.

ACTING CHAIRPERSON TRACY: Actually, you should put your name at least on the bottom of that

sheet or somewhere, so they can identify. If it is not stapled together, then if you could just put your name with that.

Then that concludes this session.

MR. DILLARD: Thank you very much. I appreciate everybody's help.

(Whereupon, the foregoing matter went off the record at 4:34 p.m.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Circulatory System Devices Panel of the Medical Devices Advisory Committee

Before: DHHS/FDA/CDRH

Date: December 4, 2000

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.